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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/721,231	Applicant(s) VANDERHOEK, JACK Y.	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/04</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to a method of stimulating prostacyclin formation in cells, which method utilizing at least one conjugated linoleic acid or its ester or a lipid containing at least one conjugated linoleic acid, classified in class 514.
 - II. Claims 17-22, , drawn to a food composition comprising a food and an additive added to the food, wherein the additives comprises at least one ester containing at least one conjugated linoleic acid, classified in class 426.
 - III. Claims 23-28, drawn to a pharmaceutical composition in tablet or capsule form which comprises, as the active component, an effective amount of at least one ester containing at least one conjugated linoleic acid, together with a pharmaceutically acceptable carrier, classified in class 424.
 - IV. Claims 29-34, drawn to a method of stimulating thromboxane formation in cells, which method comprises containing said cells with 9Z, 11Z octadecadienoic acid ,classified in class 514.
 - V. Claims 35 and 43, drawn to a food composition comprising a food and an additive added to the food, wherein the additives comprises an ester of 9Z, 11Z octadecadienoic acid, classified in class 426.

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VI. Claims 36 and 44, drawn to a pharmaceutical composition in tablet or capsule form which comprises, as the active component, an effective amount of 9Z, 11Z octadecadienoic acid and a pharmaceutically acceptable carrier, classified in class 424.

VII. Claims 37-42, drawn to a method of stimulating an release of arachidonic acid in cells which method comprises containing said cells with 9Z, 11Z octadecadienoic acid, classified in class 514.

2. Inventions I, IV, VII and II,III, V, VI are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). The claimed method can be practiced by materially different product as evidenced by numerous patents and non-patent literatures, see supporting documents US 6670138, 6417205, 6280737.

3. Inventions II, V and III, VI are directed to related to a materially different food compositions(II, V) vs a pharmaceutical composition(III, VI). The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Food composition comprises of materially different component such as food component. Although the ingredient required by the claims is existing in both food and

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pharmaceutical composition, the pharmaceutical composition consists of the said ingredient as required in combination of carrier where the carrier is not obvious variants with food or any food components, or not capable of use together, having materially different design , mode of operation, function each other.

4. Inventions I and IV and VII are independent and distinct to each others where each invention differs because they are practiced materially in the products administered. These methods require compounds which are chemically recognized as having diverse chemical structure as discussed above, and thus, they are not obvious variants or not capable of use together, having materially different design , mode of operation, function each other.

5. Inventions II and V (or III and VI) are independent and distinct to each other because each invention can be practiced with materially different ingredient(e.g. 10, 12-octadecadienoic acid vs. 9Z, 11Z octadecadienoic acid) where these ingredients are chemically recognized as having diverse chemical structure as known in the art, and thus, they are not obvious variants or not capable of use together, having materially different design , mode of operation, function each other.

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, and because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of species

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1. This application contains claims directed to more than one species of the generic invention. The species are as follows:

a. a single disclosed species for the all inventions: 10, 12-octadecadienoic acid vs. 9Z, 11Z octadecadienoic acid.

*** If 9Z, 11Z octadecadienoic acid is elected as a single disclosed species of ingredient required, and one of composition invention is elected(i.e. the food composition of invention II and V, or a pharmaceutical composition of invention III and VI), invention II and V (or invention III and VI) will be examined together since each invention is practiced with same ingredient.

b. a single disclosed species for the inventions drawn to the method: a conjugated linoleic acid vs an ester containing a conjugated linoleic acid vs a lipid.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is required, in reply to this action, to elect a **single disclosed species** (i.e. a specific compound) to which the claims shall be restricted if no generic claim is finally held to be allowable. **The reply must also identify the**

claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

1. No claim is allowed.
2. All pending claims are subject to restriction/election requirement.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
May 15, 2006
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